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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/843,961

04/27/2001

Charles Carpenter

03604-0007-CNUS02

1957

20306

7590

04/16/2004

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843,961

Applicant(s)

CARPENTER, CHARLES

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's amendment filed 9/25/2003 has been received. Claims 1-33 are pending.
2. The indicated allowability of claims 1-33 is withdrawn in view of the newly discovered references. Rejections based on the newly cited reference(s) follow.

Drawings

3. This application, filed under former 37 CFR 1.60, lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings. In unusual circumstances, the formal drawings from the abandoned parent application may be transferred by the grant of a petition under 37 CFR 1.182.

Claim Rejections - 35 USC § 112

4. Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention

Claim 1 fails to specifically set forth the invention as disclosed in the specification. Throughout the specification, the device is disclosed as a sampler member and a detection member which are capable of being separated into two parts and further capable of being assembled into one part. The assay device is disclosed as being reassembled into one part by the insertion of the sampler component into the detection component. Such a device is not specifically claimed.

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5. Claims 1-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because it is unclear where the chromatography region is located.

It is recommended that claim 1 be rewritten as follow:

A device for performing a binding pair assay comprising:

[(a)] a housing comprising a sampler member and a detection member, wherein the device is capable of being separated into at least two parts comprising the sampler member and the detection member, and the device is further capable of being assembled into one part by inserting the sampler member into the detection member such that a sample collector is placed in capillary communication contact with a chromatography medium; wherein [(b)]

(a) the detection member comprises a chromatography region comprising the chromatography medium [with] having a transit zone and a capture zone; and

(b) [(c)] the sampler member comprises a sample collector associated with the sampler member such that the sample collector is exposed to receive the sample upon separation of the device into the sampler member and the detection member[, and wherein the sample collector is in capillary communicating contact with the capture zone through the transit zone when the device is assembled].

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 1-4, 6-9, 14- 28, 31 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Chandler et al (US 5,877,028).

Chandler discloses a device comprising two components that can be separated from each other and further capable of reassembly. The first component comprises a sample preparation zone (i.e sampler member), the second component comprises a chromatographic medium having a conductor (labeled transfer pad/transit zone) where labeled binding partner may be present; a detection zone having an immobilized binding partner (capture zone) and an absorber. See column 21, lines 10 through column 24, line 38. The label can be enzyme, dye or colloidal gold. The chromatographic medium is nitrocellulose, nylon, paper or rayon etc. The device also includes window for viewing the assay results. See also figure 1.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 4,624,929

US 4,857,453

US 5,19,789

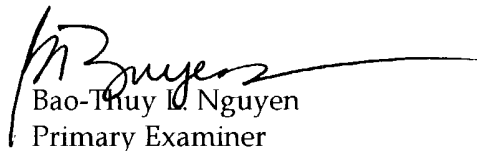
US 5,415,994

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641